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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,866	10/10/2006	Dirk Werling	E072 1070.1 (50718.0008.5	9180

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WOMBLE CARLYLE SANDRIDGE & RICE, PLLC
ATTN: PATENT DOCKETING 32ND FLOOR
P.O. BOX 7037
ATLANTA, GA 30357-0037

EXAMINER	
HORNING, MICHELLE S	
ART UNIT	PAPER NUMBER
1648	

MAIL DATE	DELIVERY MODE
04/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/566,866	WERLING, DIRK	
	Examiner	Art Unit	
	MICHELLE HORNING	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-14,18,19,21-29,38,45-48 and 50* is/are pending in the application.

4a) Of the above claim(s) *22-29,45-48 and 50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-14,18,19,21 and 38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 February 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/23/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to communication filed 2/23/2009.

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 2/23/2009 is acknowledged. The traversal is on the ground(s) that the methods require the use of the same technical feature and thus should be considered in the same group as Group I. This is not found persuasive because for claims 22-29, the special technical feature can be used for in vitro methods. Claims 45-46 require the analyses of an animal wherein the compound can be used for an in vitro test. Lastly, claims 47-48 and 50 are drawn to parts for detection. The special technical feature appears to be directed to detection methods wherein the compound can be used in vitro or vivo with or without said parts.

The argument is found to be persuasive for Group 5 and claim 38 will be considered with Group I.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This claim is directed to a list of diseases found on the OIE list A. Note that the list is expected to be regularly updated

changed and would include diseases that have yet to be discovered. Given this is a continuously evolving list, it is not clear which disease is being claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 6-11, 13, 18, 21 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Golding et al (1995).

Golding describes a compound consisting of *b. abortus* peptide conjugated to an HIV gp120 peptide. The methods for conjugation are described on p. 3300, which covalently conjugates the antigen and glycoprotein via a thioacetylation reaction. Page 3301 describes diluting the conjugates in a HEPES buffer, meeting the limitation of a pharmaceutically acceptable carrier (see instant claim 21) before administration to mice. Note that claim 9 is drawn to a compound comprising an antigen comprising 2 or more molecules. Given the b. abortus peptide consists of multiple amino acids and it is known to evoke an immune response (p. 3299-3300), this limitation is met by the prior art.

Claims 6-11, 13, 18-19, 21 and 38 are rejected under 35 U.S.C. 102(a) as being anticipated by Paoletti et al (2002).

Paoletti describes conjugates comprising HIV gp120, which is part of human immunodeficiency virus, which is associated with the infectious disease AIDS in humans, env2-3 (nonglycosylated form of gp120) and tetanus toxoid (TT) (see whole document, abstract). The steps for conjugation are found on p. 1598 forming a covalent bound on the glycoprotein by reaction from free aldehydes with the TT and the resulting conjugates were dialyzed against PBST (p. 1598). These descriptions meet the limitations of a pharmaceutically acceptable carrier and covalently linking of multiple molecules. The authors used adjuvants, including Quil A adjuvant, in combination with the conjugate vaccine (see p. 1598 and instant claim 19).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 6-14, 18-19, 21 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paoletti, Engering (2002), Kaverin (2002) and Jin and Wright (2003, ABSTRACT ONLY).

The teachings of Paoletti are applied as they are above. Paoletti does not describe an OIE list A pathogen (such as avian influenza) or an antigen on the same polypeptide chain as HIV gp120.

Engering describes the binding of DC-SIGN to HIV gp120 (see Abstract). The authors conclude that DC-SIGN is internalized upon binding of a ligand. Further, the

authors provide that bound ligands are efficiently processed and presented to CD4+ T cells to induce T cell activation. The authors conclude that the DC-SIGN receptor is an efficient DC-specific Ag receptor that can be used as a target to induce viral and antitumor immunity (see Abstract).

Kaverin characterizes the antigenic sites on the haemagglutinin molecule derived from an H5 avian influenza virus. The authors describe this virus as highly pathogenic, fatally circulating among birds and humans (see introduction).

It would have obvious for one of ordinary skill in the art to combine the teachings above and make a HIV gp120 fused to a known antigen. One would have been motivated to do so in order to present a known and characterized antigen from a highly pathogenic virus to a DC leading to the efficient induction of T cell activation by way of DC-SIGN receptor binding (see Engering). Further, protein fusion methods are commonly used and widely known; see abstract by Jin and Wright. There would have been a reasonable expectation of success given the HIV gp120 and the haemagglutinin are both well characterized and the underlying techniques are commonly used by the ordinary artisan. The invention as a whole was clearly *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHELLE HORNING whose telephone number is

(571)272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michelle Horning/
Examiner, Art Unit 1648
/Bruce Campell/
Supervisory Patent Examiner, Art Unit 1648